

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Brian Craig Lee et al.

Confirmation No.: 2047

Application No.: 10/028,450

Examiner: R. Joynes

Filing Date: Oct. 24, 2001

Group Art Unit: 1615

Title: A METHOD AND DOSAGE FORM FOR DISPENSING A BIOACTIVE SUBSTANCE

Mail Stop Appeal Brief-Patents
Commissioner For Patents
PO Box 1450
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TRANSMITTAL OF APPEAL BRIEF

Sir:

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on Aug. 11, 2004.

The fee for filing this Appeal Brief is (37 CFR 1.17(c)) \$340.00.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

() (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d) for the total number of months checked below:

- | | |
|------------------|-----------|
| () one month | \$110.00 |
| () two months | \$430.00 |
| () three months | \$980.00 |
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() The extension fee has already been filled in this application.

(X) (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account **08-2025** the sum of \$340.00. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 08-2025 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 08-2025 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,

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By

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For Application of

Dated: October 11, 2004

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Group Art Unit 1615

Serial No. : 10/028,450

Examiner R. Joynes

Filed : October 24, 2001

HP Docket No. 10010463-1

For : A METHOD AND DOSAGE FORM FOR
DISPENSING A BIOACTIVE SUBSTANCE

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P. O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

BRIEF OF APPELLANTS

This Brief is presented in opposition to the Examiner's final rejection of claims 1-8, 10-20, 23, 24, 27, 54, and 73-85 in the Office action dated June 3, 2004.

I. REAL PARTY IN INTEREST

The real party in interest is Hewlett-Packard Development Company, L.P., a Texas limited partnership, of Houston, Texas.

II. RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-85 have been presented in the application. Claims 1-8, 10-20, 23, 24, 27, 54, and 73-85 are currently pending. Claims 9, 21, 22, 25, 26, 28-53, and 55-72 have been withdrawn from consideration.

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Applicants appeal the final rejection of claims 1-8, 10-20, 23, 24, 27, 54, and 73-85.

IV. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Office action dated June 3, 2004.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 recites a method of manufacturing a bioactive fluid dose on an ingestible sheet. The method includes advancing the ingestible sheet to a dispense position (page 12, lines 25-30; Fig. 2a), and activating a fluid ejector to eject at least one drop of a bioactive fluid (page 19, lines 11-17, Fig. 6a). The method further includes dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet (page 18, lines 8-11, Figs. 4 and 6a), and forming an array of bioactive deposits on the ingestible sheet (page 19, lines 25-29, Fig. 6a).

Claim 54 recites a method of manufacturing a bioactive fluid dose on an ingestible sheet. The method includes inserting a fluid ejection cartridge into a bioactive fluid dispensing system (Figs. 1a and 2b). The cartridge includes a reservoir holding a printable bioactive fluid comprising a mixture of an ingestible ink and a bioactive fluid (page 8, lines 13-15). The method further includes advancing the ingestible sheet to a dispense position (page 12, lines 25-30; Fig. 2a), specifying a user message and printing the user message on the ingestible sheet using the printable bioactive fluid (page 25, lines 5-29).

Claim 75 recites a method of manufacturing a bioactive dosage form. The method includes advancing an ingestible sheet having at least one dosage region to a dispense position (page 12, lines 25-30; Fig. 2a), and activating a fluid ejector to

eject a drop of a bioactive fluid (page 19, lines 11-17, Fig. 6a). The method also includes dispensing the bioactive fluid in a two-dimensional array of bioactive deposits onto the dosage region (page 19, lines 25-29, Fig. 6a). The density of the two-dimensional array of bioactive deposits varies between a first edge and a second edge of the dosage region, forming a two-dimensional gradient of bioactive deposits (page 23, lines 16-20, Fig. 8a).

Claim 85 recites a method of manufacturing a bioactive dosage form. The method includes advancing an ingestible sheet having at least one dosage region to a dispense position (page 12, lines 25-30; Fig. 2a), and activating a fluid ejector to eject a drop of a bioactive fluid (page 19, lines 11-17, Fig. 6a). The method also includes dispensing the bioactive fluid in a first two-dimensional array of bioactive deposits onto the dosage region (page 19, lines 25-29, Fig. 6a). The method also includes dispensing an ingestible barrier layer on the first two-dimensional array of bioactive deposits (page 21, lines 4-6, Fig. 6b), and dispensing the bioactive fluid in a second two-dimensional array of bioactive deposits on said ingestible barrier layer, thus forming a three-dimensional array of bioactive deposits on the ingestible sheet (page 21, lines 6-31, Figs 6c and 6d).

Specific references to portions of the application are provided with the understanding that nonreferenced portions of the application may also be relevant. As such, it should be understood that the claims are not limited by the particular references made above, but rather are fully supported by the entirety of the disclosure.

VI. GROUNDS OF REJECTION

In the Official action of June 3, 2004:

Claims 1-8, 10-20, 23, 24, 27, 54, and 75-85 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Carden, Jr. et al. (US 6,086,942) in combination with Stewart (WO 95/01735).

Claim 74 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Carden in combination with Stewart and McHugh et al. (US 6,027,758).

Claim 73 was rejected under 35 U.S.C. § 112, ¶1 as failing to comply with the enablement requirement.

Claim 73 was rejected under 35 U.S.C. § 112, ¶2 as being indefinite.

VII. ARGUMENT

A. Rejection of Claims 1-8, 10-20, 23, 24, 27, 54, and 75-85 Under 35 U.S.C. §103(a) as Being Unpatentable over Carden in Combination with Stewart Is Inappropriate

The combination of Carden with Stewart does not render Applicants' invention obvious because (1) Stewart is nonanalogous art and therefore can not properly be combined with Carden; (2) there is no motivation or suggestion in the prior art as a whole to combine Stewart with Carden; and (3) even if combined, Carden and Stewart do not teach each and every element recited in Applicants' claims.

1. Stewart is Nonanalogous Art

References can be used as prior art in an obviousness determination only when analogous to the claimed invention. *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992). A two part test defines what qualifies as analogous prior art: (a) whether the art is from the same field of endeavor, regardless of the problem addressed and, (b) if the reference is not within the field of the inventor's endeavor, whether the

reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986); see also *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979).

a) *Stewart is Not from the Same Field of Endeavor as Applicants' Invention*

The field of endeavor is determined by reference to the explanations of the invention's subject matter found in the patent application. See *Wood*, 599 F.2d at 1036 (confining the field of endeavor to the scope explicitly specified in the background of the invention); see also *In re Bigio*, 2004 U.S. App. LEXIS 17981 (Fed. Cir. 2004). The application at issue sets forth the delivery of medicaments as the field of endeavor. In particular, in the Background section of the application, Applicants specify that "many individuals suffer from chronic health problems that require the regular administration of medicaments [and that] diseases such as diabetes, allergies, epilepsy, heart problems, AIDS, and even cancer requires the regular delivery of precise doses of medicaments if patients are to survive over long periods of time." Page 1, lines 25-29. The application teaches a new method for treating such individuals and/or otherwise facilitating good health by providing a new medicament delivery mechanism. Accordingly, a prior art reference should only be considered in the same field of endeavor if it deals with the delivery of medicaments for the treatment or prevention of disease or sickness, or for otherwise maintaining or improving good health.

Stewart is not concerned with maintaining or improving good health. Stewart clearly states that it "relates to devices and methods used to decorate foodstuffs, particularly baked goods, such as for example cakes and pies." Page 1, lines 5-7.



FIG. 1 FROM STEWART

Decorating cakes and pies can not fairly be considered to be in the same field of endeavor as the delivery of medicaments.

b) Stewart is Not Reasonably Pertinent to the Particular Problem with which the Inventor Is Involved

The problem faced by the Applicants is controlling the application of a medicament to a carrier. In particular, Applicants face the problem of precisely controlling the amount of medicament applied to the carrier: "Drugs with a narrow therapeutic range must also be precisely dosed. If the patient falls below the range, the desired effect will not occur. However, if the patient is above the range then the risk of toxic effects increases." Page 3, lines 4-6. In contrast, the Stewart reference is singularly focused on decorating foodstuffs. Stewart discloses a method for controlling the ornamental appearance of items such as cakes and pies. To this end, Stewart teaches printing an edible ink onto an edible film but does not indicate that precisely controlling the amount of edible ink that is applied to the edible film is important. Stewart only addresses the aesthetic appearance of the cake or pie. Decorating a cake or pie does not require anywhere near the same level of precision

as creating medicament doses. Accordingly, Stewart is not reasonably pertinent to the particular problem of precisely controlling the amount of medicament applied to a carrier.

The Examiner has improperly used hindsight in relying on Stewart. In particular, the Examiner has recognized that the cake and pie decorating invention described in Stewart can use printing, and that Applicants' invention also can use printing. However, the very different types of printing disclosed in Stewart and the application are merely solutions to the very different problems faced by Stewart and the Applicants. The aesthetic and ornamental teachings of Stewart are not logically relevant to the problems faced by the Applicants.

The Federal Circuit has stated "that it is necessary to consider 'the reality of the circumstances' - in other words, common sense - in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). Common sense dictates that a person of ordinary skill would not reasonably be expected to look to the cake and pie decorating arts to find better ways of delivering medicaments to people who have, among others, conditions such as diabetes, allergies, epilepsy, heart problems, AIDS, or cancer. Stewart is not from the same field of endeavor nor reasonably pertinent to the particular problem, and therefore is not analogous art to the application. Therefore, Stewart can not properly be used to reject claims of the application under 35 U.S.C. § 103. Accordingly, the Examiner's rejection of claims 1-8, 10-20, 23, 24, 27, 54, and 75-85 under 35 U.S.C. §103(a) as being unpatentable over Carden, in combination with Stewart should be reversed.

2. *There Is No Motivation or Suggestion in the Prior Art as a Whole to Combine Carden with Stewart*

To reject claims under 35 U.S.C. §103 an examiner must factually support a prima facie conclusion of obviousness. When the rejection depends on a combination of prior art references, there must be some motivation or suggestion to combine the references. The motivation or suggestion to combine may come from the prior art references themselves or the knowledge generally available to one of ordinary skill in the art.

The Examiner has not factually supported a prima facie conclusion of obviousness because the Examiner has not identified a proper motivation or suggestion to combine Carden and Stewart. On the contrary, the Examiner instead concludes without factual support:

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to print bioactive fluid on an edible or ingestible sheet that further includes writing or a message that is achieved with edible colored ink.

One of ordinary skill in the art would have been motivated to do this to produce a product that delivers precise amounts of the bioactive fluid that are specific to the prescription required for a particular patient or application.

Page 5, Official action dated June 3, 2004 (emphasis added).

In this statement the Examiner suggests that the motivation to combine Carden and Stewart is derived from the desire to deliver precise amounts of bioactive fluid. However, neither Carden nor Stewart even discusses delivering precise amounts of bioactive fluid. The Examiner apparently is using the Applicants' disclosure, which does describes the desire to deliver precise amounts of bioactive fluid, as a template for combining Carden and Stewart. This is inappropriate because the motivation or suggestion to make the claimed combination can not come from the disclosure of the applicant. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Furthermore, there is no motivation or suggestion to combine references if the proposed combination would render the prior art unsatisfactory for its intended purpose. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). On Page 4 of the Official action dated June 3, 2004, the Examiner states that “Carden does not expressly teach the substrate as an edible substrate.” To overcome this deficiency, the Examiner replaces the surgical implant of Carden with the edible substrate of Stewart. Such a replacement would render Carden unsatisfactory for treating tumors because the substrate of Stewart “is so gossamer that it will essentially disappear when applied to a foodstuff.” (page 19) Carden requires a substrate that does not dissolve or alternatively a biodegradable plastic that can dissolve, but only after radioactive isotopes decay to a biologically acceptable level. (col. 20, lines 35-38). The gossamer substrate of Stewart would dissolve almost immediately upon being surgically implanted in or near a tumor. Because the modifications suggested by the Examiner would render Carden unsatisfactory in treating tumors, there is no motivation or suggestion to combine the references. Similarly, modification of Stewart with Carden produces radioactive cakes and pies, which clearly renders Stewart unsatisfactory for its intended purpose of decorating edible food items. Therefore, the combination of Carden and Stewart is inappropriate and rejection of claims 1-8, 10-20, 23, 24, 27, 54, and 75-85 under 35 U.S.C. §103(a) as being unpatentable over Carden in combination with Stewart should be reversed.

3. *The Combination of Carden and Stewart Does Not Teach Each and Every Element Recited in Claims 1-8, 10-20, 23, 24, 27, 54, and 75-85*

Even if Stewart is found to be analogous art and it is determined that a motivation or suggestion to combine Carden and Stewart exists, a *prima facie* case

of obviousness has not been established because Carden and Stewart do not teach all of the features found in claims 1-8, 10-20, 23, 24, 27, 54, and 75-85. Among other features, claim 1 recites advancing an ingestible sheet to a dispense position, and activating a fluid ejector to eject at least one drop of a bioactive fluid onto the sheet.

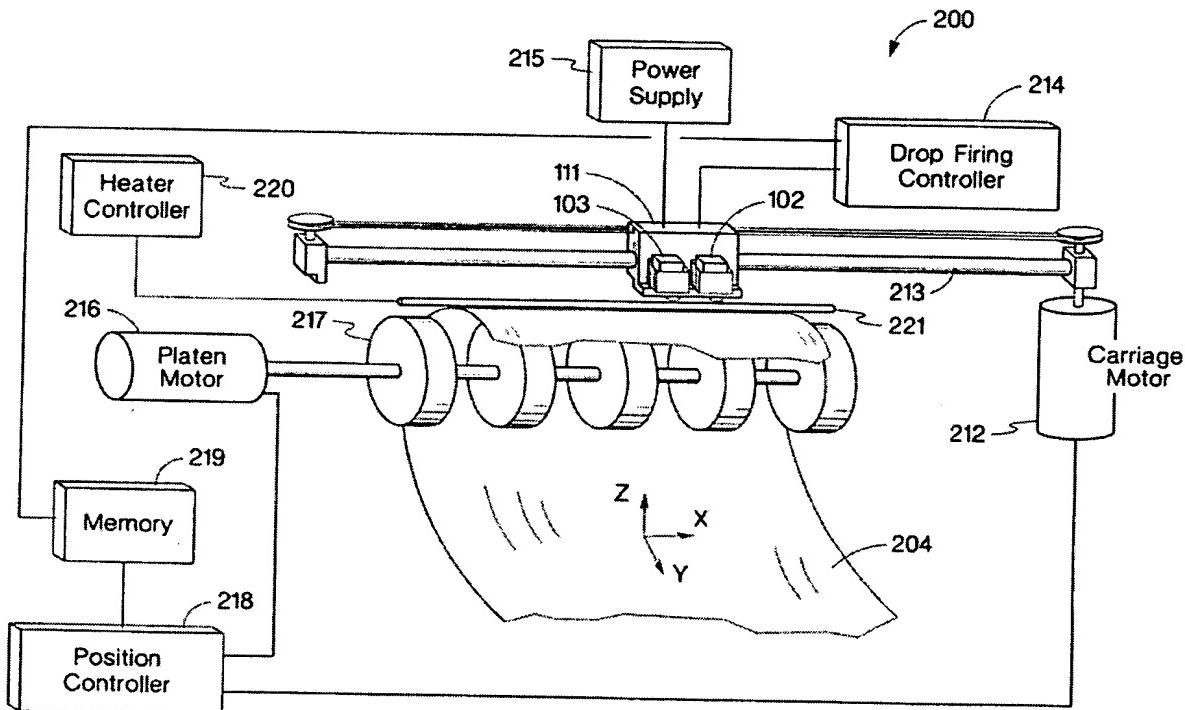


Fig. 2a

Applicant's disclosure supports such a feature in Fig. 2a and on at least pages 12 and 13. However, the Examiner has not identified an explicit teaching in either Carden or Stewart that shows advancing the ingestible sheet to a dispense position, and activating a fluid ejector to eject at least one drop of a bioactive fluid onto the sheet. Accordingly, Carden and Stewart can not render claim 1 obvious.

If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending from that claim is also nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Accordingly, claims 2-8, 10-20, 24, and 27 are nonobvious because they

depend from nonobvious claim 1. Many of these dependent claims include further features that are not disclosed by either Carden or Stewart, and therefore such dependent claims are nonobvious based on those features as well. For example, claims 10-15 depend from claim 1 and further require dispensing the bioactive fluid onto a dosage form having a first edge and a second edge, wherein the density of the bioactive deposits varies between the first edge and the second edge, whereby a gradient in a bioactive agent is formed. As acknowledged by the Examiner on page 5 of the Official action dated June 3, 2004, "Neither reference teaches the gradient composition recited in instant claims 9-15." The Examiner has admitted that neither Carden nor Stewart disclose the gradient feature recited in claims 10-15. Furthermore, the Examiner has not provided any reference in which a gradient is disclosed. Accordingly, for at least this additional reason, Carden and Stewart can not render claims 10-15 obvious.

While the Examiner has acknowledged that Carden and Stewart fail to disclose features recited in claims 10-15, other dependent claims are not specifically addressed. In the case of some claims, the Examiner has cited portions of Carden or Stewart that presumably are supposed to disclose the claimed subject matter. However, the cited material does not in fact disclose what is claimed. For example, claim 7 recites activating a second fluid ejector to eject a barrier component fluid over the dispensed bioactive fluid.

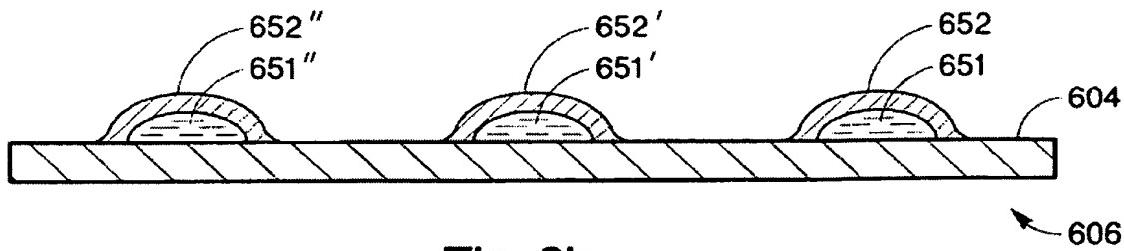


Fig. 6b

Applicant's disclosure supports such a claim in Fig. 6b and on at least pages 19 and 20, where an ejected barrier layer 652 is disclosed. Without specifically referring to claim 7, the Examiner has stated that at Column 8, lines 50-65 Carden discloses that "[t]he substrate is further coated with a sealing layer or layers." However, an ejected barrier layer is not disclosed in the referenced passage, or in any other portion of Carden for that matter. Carden merely discloses a "plastic coat, a titanium shell, or other suitable radiation transparent material" that can be used with "a hollow-tube brachytherapy device." Because neither Carden nor Stewart discloses activating a second fluid ejector to eject a barrier component fluid over the dispensed bioactive fluid, claim 7 can not be rendered obvious by Carden and Stewart.

Claims 7 and 10-15 are examples of dependent claims that the Examiner has rejected even though neither Carden nor Stewart discloses all of the features of those claims. The following dependent claim features are further examples of features that are not disclosed: claim 2 recites printing manufacturing information onto the ingestible sheet, claim 3 recites printing the manufacturing information onto the ingestible sheet in a machine detectable form, claim 4 recites printing the manufacturing information onto the ingestible sheet in a human-perceptible form, claim 6 recites sealing the dispensed bioactive fluid on the ingestible sheet, claim 8

recites activating said first fluid ejector to eject a predetermined number of ejections of the bioactive fluid, claim 16 recites depositing essentially a drop of a bioactive fluid onto the ingestible sheet wherein the fluid is in the range of from about ten femtoliters to about ten microliters volume, claim 18 recites dispensing the bioactive fluid in overlapping deposits forming essentially a layer of the bioactive fluid, claim 19 recites activating a second fluid ejector to dispense at least a drop of a second bioactive fluid onto the ingestible sheet, claim 20 recites activating a plurality of fluid ejectors to eject at least a drop of a plurality of bioactive fluids, and wherein the step of dispensing further comprises the step of dispensing the plurality of bioactive fluids in a plurality of two dimensional arrays on a plurality of ingestible sheets wherein the plurality of bioactive fluids are different, claim 23 recites activating a plurality of fluid ejectors to eject at least a drop of a plurality of bioactive fluids, and wherein the step of dispensing further comprises the step of dispensing the plurality of bioactive fluids in a plurality of two dimensional arrays on a plurality of ingestible sheets wherein the plurality of bioactive fluids are different, claim 24 recites a bioactive fluid dose produced by the method of claim 23, and claim 27 recites printing user information on the ingestible sheet. These claims should not be considered obvious because neither Carden nor Stewart discloses the dependent features recited in these claims and set forth above.

Independent claim 54 recites, among other features, specifying a user message, and printing the user message on the ingestible sheet using a mixture of ingestible ink and a bioactive fluid.

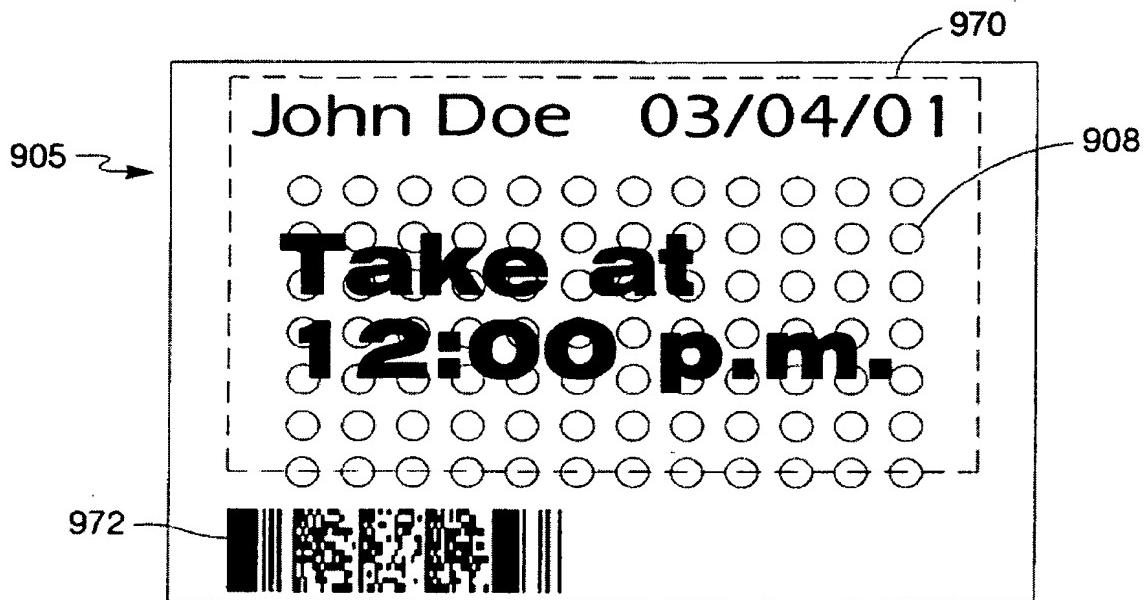


Fig. 9b

Applicant's disclosure supports such a claim in Fig. 9b and on at least pages 8, 9, 25, and 30. Neither Carden nor Stewart discloses mixing an ingestible ink with a bioactive fluid, let alone using such a mixture to print a user message. Without referring specifically to claim 54, the Examiner has stated that at Column 16, lines 17-26, Carden discloses that "The substrate can also include the simultaneous application of colored ink and radioactive material to mark or code the outer surface of the substrate." However, a user message printed from a mixture of ingestible ink and bioactive fluid is not disclosed in the referenced passage, or in any other portion of Carden for that matter. Carden merely discloses color coding brachytherapy devices. Because neither Carden nor Stewart discloses specifying a user message, and because neither discloses printing the user message on the ingestible sheet using a mixture of ingestible ink and a bioactive fluid, claim 54 can not be rendered obvious by Carden and Stewart.

Independent claim 75 recites, among other features, dispensing said bioactive fluid in a two-dimensional array of bioactive deposits onto said at least one dosage region, said dosage region having a first edge and a second edge, wherein the density of the two-dimensional array of bioactive deposits varies between the first edge and the second edge, forming a two-dimensional gradient of bioactive deposits. As discussed above with reference to claims 10-15, the Examiner has acknowledged that neither Carden nor Stewart teaches a gradient composition. Accordingly, claim 75 can not be rendered obvious by Carden and Stewart.

As explained above, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending from that claim is also nonobvious. Accordingly, dependent claims 76-84 are nonobvious for at least the reasons stated above with reference to claim 75. Furthermore, the following dependent features are not disclosed in the cited prior art: claim 76 recites coating said bioactive deposits with an ingestible coating material, claim 77 recites activating a second fluid ejector to eject an ingestible barrier component fluid over the dispensed bioactive fluid, claim 78 recites forming said ingestible sheet into a three-dimensional gradient of bioactive deposits having a bioactive agent, claim 79 recites forming said ingestible sheet into a three-dimensional gradient of bioactive deposits having a bioactive agent, claim 80 recites forming the three-dimensional gradient of bioactive deposits to provide a dosage form wherein after being ingested the amount of the bioactive agent released decreases over time, claim 81 recites forming the three-dimensional gradient of bioactive deposits to provide a dosage form wherein after being ingested the amount of the bioactive agent released remains constant over time, claim 82 recites forming the three-dimensional gradient of bioactive deposits to provide a dosage form

wherein after being ingested a discrete amount of the bioactive agent is released in a repeatable manner over time, claim 83 recites forming the three-dimensional gradient of bioactive deposits to provide a dosage form wherein after being ingested a discrete amount of the bioactive agent is released over different times, and claim 84 recites a bioactive dosage form produced by the method of claim 75. In addition to the reasons set forth with respect to independent claim 75, these claims should not be considered obvious because neither Carden nor Stewart discloses the dependent features set forth above.

Independent claim 85 recites, among other features, dispensing an ingestible barrier layer on top of a two-dimensional array of bioactive fluid, and dispensing more bioactive fluid on top of the barrier layer to form a three-dimensional array of bioactive deposits. As discussed above with reference to claim 7, neither Carden nor Stewart teaches an ingestible barrier layer, let alone a three dimensional array of deposits formed by dispensing bioactive fluid on the ingestible barrier layer. Accordingly, claim 85 can not be rendered obvious by Carden and Stewart.

B. Rejection of Claim 74 Under 35 U.S.C. §103(a) as Being Unpatentable over Carden, Jr. et al. in Combination with Stewart and McHugh et al. Is Inappropriate

Claim 74 recites dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet having a restructured fruit or vegetable material disposed on or within the ingestible sheet. Claim 74 depends from nonobvious claim 1, and therefore is not obvious for at least the reasons stated above with reference to claim 1. *In re Fine* at 1071. In addition, the rejection of claim 74 should be reversed because McHugh is not analogous art and because there is no motivation or suggestion to combine McHugh with Carden and Stewart.

McHugh is not analogous art because it is not from the same field of endeavor as Applicants' invention and it is not reasonably pertinent to the particular problem with which the inventor is involved. In particular, "the prime objective of [McHugh is] to provide value added, restructured fruit and vegetable products ... to be eaten out of hand or incorporated into baked, canned and/or frozen foods." Making restructured fruit and vegetable products can not fairly be said to be in the same field of endeavor as the delivery of medicaments, nor can it be considered reasonably pertinent to the problems associated with precisely controlling the amount of medicament applied to a carrier. Therefore, McHugh is not analogous art.

The Examiner has not identified a proper motivation or suggestion for combining Carden, Stewart, and McHugh. As described above, there is no motivation or suggestion to combine references if the proposed combination would render the prior art unsatisfactory for its intended purpose. *In re Gordon*. Carden teaches the surgical implantation of a brachytherapy device, an operation which must remain sterile to prevent the formation of infection-causing bacteria. The insertion of a restructured fruit and vegetable product into a surgical incision runs contrary to the desire of preventing bacteria growth. A restructured fruit and vegetable product would effectively serve as a fertile medium for bacteria to grow. Accordingly, the proposed combination would render Carden unsatisfactory for its intended purpose, meaning that a *prima facie* case of obviousness has not been established. Therefore, rejection of claim 74 should be reversed.

C. Rejection of Claim 73 Under 35 U.S.C. §112, ¶1 as Failing to Comply with the Enablement Requirement Is Inappropriate

Claim 73 is enabled because a person of ordinary skill in the art can practice the invention recited in claim 73 without undue experimentation. Claim 73 recites dispensing a bioactive fluid onto an ingestible sheet that has a water-expandable foam disposed on or within the ingestible sheet. The Examiner's position that one of ordinary skill in the art could not dispense a bioactive fluid onto an edible sheet that has a water-expandable foam disposed on or within the sheet is unfounded. Water expandable foams are well known, and specific examples of water-expandable foams are provided in the specification. The level of experimentation required to produce an ingestible sheet that has a water-expandable foam disposed on the sheet is much lower than the level of experimentation that is routine in the pharmaceutical industry. Accordingly, undue experimentation is not required and the rejection of claim 73 based on 35 USC §112, ¶1 should be reversed.

D. Rejection of Claim 73 under 35 U.S.C. §112, ¶2 as Being Indefinite Is Inappropriate

Claim 73 is definite because the ingestible sheet remains an ingestible sheet even if a water-expandable foam is disposed on or within the sheet. The Examiner has taken the position that the water-expandable foam is not ingestible, which is not true. Even if this is true, it does not mean that the sheet itself is not ingestible. If the water-expandable foam is not ingestible then the combination of the sheet and the water-expandable foam may not be ingestible, but the ingestible sheet itself remains an ingestible sheet. Claim 73 does not recite that the combination of the sheet and the water-expandable foam is ingestible, but rather that the sheet itself is ingestible. Accordingly, rejection of claim 73 based on 35 USC §112, ¶2 should be reversed.

E. Conclusion

The rejection of claims 1-8, 10-20, 23, 24, 27, 54, and 73-85 is improper because claims 1-8, 10-20, 23, 24, 27, 54, and 75-85 are not obvious in view of Carden and Stewart, claim 74 is not obvious in view of Carden, Stewart, and McHugh, and claim 73 is definite and enabled. Accordingly, the rejection of all pending claims should be reversed.

VIII. CLAIMS APPENDIX

1. A method of manufacturing a bioactive fluid dose on an ingestible sheet, comprising the steps of:
 - advancing the ingestible sheet to a dispense position;
 - activating a fluid ejector to eject at least one drop of a bioactive fluid;
 - dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet; and
 - forming an array of bioactive deposits on the ingestible sheet.
2. The method of claim 1, further comprising the step of printing manufacturing information onto the ingestible sheet.
3. The method of claim 2, wherein said step of printing further comprises the step of printing said manufacturing information onto the ingestible sheet in a machine detectable form.
4. The method of claim 2, wherein said step of printing further comprises the step of printing said manufacturing information onto the ingestible sheet in a human-perceptible form.
5. The method of claim 2, wherein said step of printing further comprises the step of ejecting an ingestible ink from at least one ink ejector fluidically coupled to an ink reservoir onto the ingestible sheet.

6. The method of claim 1, further comprising the step of sealing the dispensed bioactive fluid on the ingestible sheet.

7. The method of claim 6, wherein the step of sealing further comprises the step of activating a second fluid ejector to eject a barrier component fluid over the dispensed bioactive fluid.

8. The method of claim 1, wherein the step of activating further comprises the step of activating said first fluid ejector to eject a predetermined number of ejections of the bioactive fluid.

10. The method of claim 1, wherein the step of dispensing further comprises dispensing the bioactive fluid onto a dosage form having a first edge and a second edge, wherein the density of the bioactive deposits varies between the first edge and the second edge, whereby a gradient in a bioactive agent is formed.

11. The method of claim 10, wherein the step of dispensing further comprises dispensing the bioactive fluid onto the dosage form having the gradient in the bioactive agent adapted to provide an increasing dosage form wherein after being ingested the amount of the bioactive agent released increases over time.

12. The method of claim 10, wherein the step of dispensing further comprises dispensing the bioactive fluid onto the dosage form having the gradient in the bioactive agent adapted to provide a decreasing dosage form wherein after being ingested the amount of the bioactive agent released decreases over time.

13. The method of claim 10, wherein the step of dispensing further comprises dispensing the bioactive fluid onto the dosage form having the gradient in the bioactive agent adapted to provide a constant dosage form wherein after being ingested the amount of the bioactive agent released remains constant over time.

14. The method of claim 10, wherein the step of dispensing further comprises dispensing the bioactive fluid onto the dosage form having the gradient in the bioactive agent adapted to provide a repeatable dosage form wherein after being ingested a discrete amount of the bioactive agent is released in a repeatable manner over time.

15. The method of claim 10, wherein the step of dispensing further comprises dispensing the bioactive fluid onto the dosage form having the gradient in the bioactive agent adapted to provide a varying dosage wherein after being ingested a discrete amount of the bioactive agent is released over different times.

16. The method of claim 1, wherein the step of dispensing further comprises the step of depositing essentially a drop of a bioactive fluid onto the ingestible sheet wherein the fluid is in the range of from about ten femtoliters to about ten microliters volume.

17. A bioactive fluid dose on an ingestible sheet produced by the method of claim 1.

18. The method of claim 1, wherein the step of dispensing further comprises the step of dispensing the bioactive fluid in overlapping deposits forming essentially a layer of the bioactive fluid.

19. The method of claim 1, wherein the step of activating further comprises the step of activating a second fluid ejector to dispense at least a drop of a second bioactive fluid onto the ingestible sheet.

20. The method of claim 1, wherein the step of activating further comprises the step of activating a plurality of fluid ejectors to eject at least a drop of a plurality of bioactive fluids, and wherein the step of dispensing further comprises the step of dispensing the plurality of bioactive fluids in a plurality of two dimensional arrays on a plurality of ingestible sheets wherein the plurality of bioactive fluids are different.

23. The method of claim 1, wherein the step of activating further comprises the step of activating a plurality of fluid ejectors to eject at least a drop of a plurality of bioactive fluids, and wherein the step of dispensing further comprises the step of dispensing the plurality of bioactive fluids in a plurality of two dimensional arrays on a plurality of ingestible sheets wherein the plurality of bioactive fluids are different.

24. A bioactive fluid dose produced by the method of claim 23.

27. The method of claim 1, further comprising the step of printing user information on the ingestible sheet.

54. A method of manufacturing a bioactive fluid dose on an ingestible sheet comprising the steps of:

inserting a fluid ejection cartridge into a bioactive fluid dispensing system, said cartridge having a mixture of an ingestible ink and a bioactive fluid in a reservoir forming a printable bioactive fluid;

advancing the ingestible sheet to a dispense position;

specifying a user message; and

printing said user message on the ingestible sheet using said printable bioactive fluid.

73. The method of claim 1, wherein the step of dispensing the bioactive fluid further comprises dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet having a water-expandable foam disposed on or within the ingestible sheet.

74. The method of claim 1, wherein the step of dispensing the bioactive fluid further comprises dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet having a restructured fruit or vegetable material disposed on or within the ingestible sheet.

75. A method of manufacturing a bioactive dosage form, comprising:
advancing an ingestible sheet having at least one dosage region to a dispense position;
activating a fluid ejector to eject a drop of a bioactive fluid; and
dispensing said bioactive fluid in a two-dimensional array of bioactive deposits onto said at least one dosage region, said dosage region having a first edge and a second edge, wherein the density of the two-dimensional array of bioactive deposits varies between the first edge and the second edge, forming a two-dimensional gradient of bioactive deposits.

76. The method of claim 75, further comprising coating said bioactive deposits with an ingestible coating material.

77. The method of claim 76, wherein coating said deposits further comprises activating a second fluid ejector to eject an ingestible barrier component fluid over the dispensed bioactive fluid.

78. The method of claim 75, further comprising forming said ingestible sheet into a three-dimensional gradient of bioactive deposits having a bioactive agent.

79. The method of claim 78, further comprising forming the three-dimensional gradient of bioactive deposits to provide a dosage form wherein after being ingested the amount of the bioactive agent released increases over time.

80. The method of claim 78, further comprising forming the three-dimensional gradient of bioactive deposits to provide a dosage form wherein after being ingested the amount of the bioactive agent released decreases over time.

81. The method of claim 78, further comprising forming the three-dimensional gradient of bioactive deposits to provide a dosage form wherein after being ingested the amount of the bioactive agent released remains constant over time.

82. The method of claim 78, further comprising forming the three-dimensional gradient of bioactive deposits to provide a dosage form wherein after being ingested a discrete amount of the bioactive agent is released in a repeatable manner over time.

83. The method of claim 78, further comprising forming the three-dimensional gradient of bioactive deposits to provide a dosage form wherein after being ingested a discrete amount of the bioactive agent is released over different times.

84. A bioactive dosage form produced by the method of claim 75.

85. A method of manufacturing a bioactive dosage form, comprising:
advancing an ingestible sheet having at least one dosage region to a
dispense position;
activating a fluid ejector to eject a drop of a bioactive fluid; and
dispensing said bioactive fluid in a first two-dimensional array of bioactive
deposits onto said at least one dosage region;
dispensing an ingestible barrier layer on said first two-dimensional array of
bioactive deposits; and
dispensing said bioactive fluid in a second two-dimensional array of bioactive
deposits on said ingestible barrier layer forming a three-dimensional array of
bioactive deposits on said ingestible sheet.

IX. EVIDENCE APPENDIX

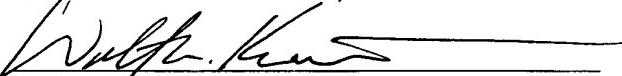
None presented.

X. RELATED PROCEEDINGS APPENDIX

None presented.

Respectfully submitted,

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